

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 200412F-0422	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/JP2004/019437	International filing date (day/month/year) 24.12.2004	Priority date (day/month/year) 26.12.2003	
International Patent Classification (IPC) or national classification and IPC A61K31/365, A23L1/30, A61P35/00, C07D307/33			
Applicant Tokyo University of Agriculture and Technology TLO Co., Ltd.			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of 4 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

PCT/JP2004/019437

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:

 - international search (Rule 12.3 and 23.1(b))
 - publication of the international application (Rule 12.4)
 - international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished

the description:

pages 1, 4-19 as originally filed/furnished

pages* 2-3, 3/1 received by this Authority on 26.10.2005

pages* _____ received by this Authority on _____

the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1-5 received by this Authority on 26.10.2005

nos.* _____ received by this Authority on _____

the drawings:

sheets 1/5-5/5 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. The amendments have resulted in the cancellation of:

the description, pages _____

the claims, nos. _____

the drawings, sheets/figs _____

the sequence listing (*specify*): _____

any table(s) related to sequence listing (*specify*): _____
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages _____

the claims, nos. _____

the drawings, sheets/figs _____

the sequence listing (*specify*): _____

any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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1. Statement

Novelty (N)	Claims	1–3	YES
	Claims	4–5	NO
Inventive step (IS)	Claims		YES
	Claims	1–5	NO
Industrial applicability (IA)	Claims	1–5	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: US 2003-0118676 A (Council of Scientific and Industrial Research), 26 June 2003

Document 2: JP 11-221048 A (Archer Daniels Midland Co.), 17 August 1999

Document 3: JP 2003-63971 A (Tama Biochemical Co., Ltd.), 5 March 2003

Document 4: JP 2002-541158 A (Hormos Nutraceutical OY Ltd.), 3 December 2002

Document 5: Phytochemicals in Human Health Protection, Nutrition and Plant Defense, 1999, pages 51 to 65

Document 6: JP 1-228928 A (Tsumura & Co.), 12 September 1989

[1] The invention set forth in claims 4 and 5 lacks novelty in the light of documents 2 to 5 cited in the international search report.

Document 2 (claims 18, 61 and 62) sets forth a food containing enterolactone.

Document 3 (paragraphs [0016] and [0019]) sets forth a food containing a lignan precursor of enterolactone.

Document 4 (claims 1 and 10; paragraph [0009]) sets forth a functional food containing a lignan precursor of

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enterolactone.

Document 5 (table 1) sets forth a food containing enterolactone.

In contrast, the food of the invention set forth in claims 4 and 5 is used "for improving fat metabolism abnormalities", and although this feature is not disclosed in documents 2 to 5, in the technical field of food, this food cannot be distinguished, even if the food is specified by functional properties.

[2] The invention set forth in claims 1 to 3 does not involve an inventive step in the light of document 1 cited in the international search report.

Document 1 (tables 1 and 3) indicates that matairesinol which is a lignan precursor of enterolactone has an activity of suppressing the proliferation of hepatoma, therefore a person skilled in the art would be able to verify the activity of suppressing the proliferation of hepatoma of different types of lignan precursors similar to matairesinol as necessary.

Moreover, although document 1 does not set forth the apoptosis inducing activity, cell cycle stoppage activity and fat metabolism abnormality improving activity of said precursor, the applicable disorder for the composition set forth in claims 1 to 3 of this application is hepatoma, therefore the effect of the invention of this application is not particularly marked.

[3] The invention set forth in claims 1 to 5 does not involve an inventive step in the light of document 6 cited in the international search report.

Document 6 (claim 7) indicates that enterolactone

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has anti-cancer activity, therefore a person skilled in the art would be able to attempt to use said lactone in the treatment of hepatoma, which is a specific cancer, as necessary.

In addition, a person skilled in the art would be able to add the enterolactone set forth in document 6 to a food as necessary.

[4] The invention set forth in claims 1 and 2 does not involve an inventive step in the light of documents 2 to 5 cited in the international search report.

Documents 2 to 5 indicate that enterolactone or a lignan derivative of said lactone has anti-cancer activity, therefore a person skilled in the art could attempt to apply these compounds to the treatment of hepatoma, which is a specific cancer, as necessary.